



General

Guideline Title

Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians.

Bibliographic Source(s)

Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P, Clinical Guidelines Committee of the American College of Physicians. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2014 Sep 16;161(6):429-40. [163 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the overall quality of evidence (high, moderate, low, insufficient) and the strength of the recommendations (strong, weak) are provided at the end of the "Major Recommendations" field.

Recommendation 1: The American College of Physicians (ACP) recommends first-line treatment with pelvic floor muscle training (PFMT) in women with stress urinary incontinence (UI). (Grade: strong recommendation, high-quality evidence)

PFMT increased continence rates and improved UI and quality of life in women with stress UI. Nonpharmacologic therapy with PFMT should be first-line treatment for women with UI.

Recommendation 2: ACP recommends bladder training in women with urgency UI. (Grade: strong recommendation, moderate-quality evidence)

Bladder training improved UI for women with urgency UI. The addition of PFMT to bladder training did not improve continence compared with bladder training alone for urgency UI.

Recommendation 3: ACP recommends PFMT with bladder training in women with mixed UI. (Grade: strong recommendation, moderate-quality evidence)

PFMT combined with bladder training improved continence and UI in women with mixed UI.

Recommendation 4: ACP recommends against treatment with systemic pharmacologic therapy for stress UI. (Grade: strong recommendation, low-

quality evidence)

Treatment of stress UI with standard pharmacologic therapies used for urgency UI has not been shown to be effective. Vaginal estrogen formulations improved continence and stress UI, but transdermal estrogen patches worsened UI.

Recommendation 5: ACP recommends pharmacologic treatment in women with urgency UI if bladder training was unsuccessful. Clinicians should base the choice of pharmacologic agents on tolerability, adverse effect profile, ease of use, and cost of medication. (Grade: strong recommendation, high-quality evidence)

Pharmacologic therapies were effective and equally efficacious at managing urgency UI and had a moderate magnitude of benefit in achieving continence rates. However, they were associated with adverse effects and evidence showed that some patients were likely to discontinue pharmacologic treatment because of these effects. For urgency UI, oxybutynin, tolterodine, darifenacin, solifenacin, fesoterodine, and trospium increased continence rates and improved UI.

Evidence was insufficient to evaluate the comparative effectiveness of different drugs and to determine the long-term safety of pharmacologic treatments for UI. Patient characteristics, such as age, race, comorbid conditions, or baseline UI, did not affect the outcomes of the various pharmacologic medications. However, adherence to pharmacologic treatments for UI was poor.

Adverse effects were a major reason for treatment discontinuation. Clinicians and their patients should compare the risk for pharmacologic adverse effects with the severity and bothersomeness of the patient's symptoms. Appendix Table 2 in the original guideline document shows the quality of evidence for outcomes of continence and improvement of UI as well as the adverse effects for the various drugs.

Evidence was insufficient to evaluate the comparative effectiveness of nonpharmacologic versus pharmacologic treatments for UI, and nonpharmacologic treatment should be considered first-line therapy. Evidence showed that nonpharmacologic treatments were better than no treatment in achieving continence and improving UI with a large magnitude of effect and are associated with a low risk for adverse effects. Pharmacologic treatments are associated with adverse effects that may be intolerable and lead to discontinuation of treatment. Clinicians and patients should keep in mind the costs of treatment, especially long-term costs, when choosing treatment.

Recommendation 6: ACP recommends weight loss and exercise for obese women with UI. (Grade: strong recommendation, moderate-quality evidence)

Weight loss and exercise improved UI in obese women with no evident harms. In addition, the benefits of weight loss in obese women extend beyond improvement of UI.

Definitions:

Grading of Quality of Evidence

High-Quality Evidence: Evidence is considered high quality when it is obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change confidence in the estimate of effect.

Moderate-Quality Evidence: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on confidence in the estimate of effect and may change the estimate.

Low-Quality Evidence: Evidence obtained from observational studies would typically be rated as low quality because of the risk for bias. Low-quality evidence means that further research is very likely to have an important effect on confidence in the estimate of effect and will probably change the estimate. However, the quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose-response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

Insufficient Evidence to Determine Net Benefits or Risks: When the evidence is insufficient to determine for or against routinely providing a service, the recommendation was graded as "insufficient evidence to determine net benefits or risks." Evidence may be conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect that is very uncertain as evidence is either unavailable or does not permit a conclusion.

The American College of Physicians Guideline Grading System*		
Quality of Evidence	Strength of Recommendation	
	Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits	Benefits Finely Balanced with Risks and Burden
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or risks		

*Adopted from the classification developed by the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Working Group.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Urinary incontinence (UI), including

- Stress UI
- Urgency UI
- Mixed UI

Other Disease/Condition(s) Addressed

Obesity

Guideline Category

Management

Treatment

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Obstetrics and Gynecology

Urology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To present the evidence and provide clinical recommendations on the nonsurgical management of urinary incontinence (UI) in women

Target Population

Women with urinary incontinence (UI)

Interventions and Practices Considered

1. Pelvic floor muscle training (PFMT)
2. Bladder training
3. Pharmacologic treatment for urgency urinary incontinence (UI) (oxybutynin, tolterodine, darifenacin, solifenacin, fesoterodine, trospium)
4. Weight loss and exercise
5. Systemic pharmacologic therapy for stress UI (not recommended)

Major Outcomes Considered

- Quality-of-life
- Continence
- Adverse effects of pharmacologic treatment
- Effects of obesity on incontinence
- Improvements in urinary incontinence

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Minnesota Evidence-based Practice Center (EPC) (see the "Availability of Companion Documents" field).

Literature Search Strategy and Eligibility Criteria

Search Strategy

The EPC sought studies from a wide variety of sources, including MEDLINE® via OVID and via PubMed®, the Cochrane Library, SCIRUS, Google Scholar, and manual searches of reference lists from systematic reviews, the proceedings of the International Continence Society (ICS), and systematic reviews by the International Consultation on Incontinence (ICI). They also reviewed grey literature packets from the Scientific Resource Center (SRC) (see Appendix Table A1 in the evidence review [see the "Availability of Companion Documents" field]). This search included regulatory documents and conducted clinical trials. The regulatory documents included medical and statistical reviews from the U.S. Food and Drug Administration (FDA), Health Canada - Drug Monographs, and Authorized Medicines for the European Union - Scientific Discussions. The EPC searched the Web site www.ClinicalTrials.gov on May 20, 2010, to find closed studies of urinary incontinence (UI) or overactive bladder. In addition, the following clinical trial registries were searched for completed trials related to the key questions: Current Controlled Trials (United Kingdom), Clinical Study Results (Pharmaceutical Research and Manufacturers of America), and World Health Organization Clinical Trials (International). Scopus and Physical Education Index was searched for conference papers and abstracts related to UI. They identified ongoing studies in ClinicalTrials.gov and the National Institutes of Health Research Portfolio Online Reported Tools (report) <http://report.nih.gov/index.aspx> Web sites.

The search strategies for the three research questions are described in Appendix A in the evidence review (see the "Availability of Companion Documents" field). Exact search strategies were developed through consultation with qualified librarians and guided by the SRC. The EPC developed an a priori search strategy based on relevant medical subject headings (MeSH) terms, text words, and weighted word frequency algorithms to identify related articles. They documented each recommended, included, and excluded study in the master library. The EPC identified studies published in English from 1990 until December 30, 2011.

Excluded references are shown in Appendix B in the evidence review. The analysis of the results from ongoing studies is presented in Appendix C of the evidence review (see the "Availability of Companion Documents" field). The protocol was developed with input from the Technical Expert Panel.

The literature search was updated on December 10, 2013 and added 201 references to the library after removing duplicates.

Eligibility

Three investigators independently determined the eligibility of the studies according to recommendations from the Cochrane Manual for Systematic Reviews. The algorithm to define study eligibility was developed for each research question (see Appendix Table D1 in the evidence review [see the "Availability of Companion Documents" field]). They followed the Comparative Effectiveness Manual to select evidence from controlled trials and observational studies. They defined the target population, eligible independent and dependent variables, outcomes, time, and setting following the population, interventions, comparators, outcomes, and settings (PICOS) framework (see Appendix Table D2 in the evidence review [see the "Availability of Companion Documents" field]). They formulated a list of eligible interventions following the discussion with key informants and technical experts, and after considering public comments (see Appendix Table D3 in the evidence review [see the "Availability of Companion Documents" field]). They included nonsurgical, nonpharmacological treatments for UI. They included the drugs available in the United States for predominant stress UI (topical estrogens and antidepressants) and those approved by the FDA for overactive bladder (see Appendix Table D4 in the evidence review [see the "Availability of Companion Documents" field]). They excluded systemic estrogens and selective estrogen receptor modulators that failed to prevent or improve UI. They included bulking agents and ingestible neurotoxins to review all nonsurgical treatment options for women with refractory UI. They reviewed abstracts to exclude news, reviews, letters, comments, and case reports. Then they confirmed eligible target populations of adult women residing in the community.

Inclusion Criteria

- Studies published in English after 1989.
- Studies that examined eligible interventions of drug therapies or nonsurgical treatments for women with UI.
- Studies that examined eligible outcomes of UI (total, mixed, stress, urgency), quality of life in women with UI, and harms of the treatments.

The EPC included all randomized controlled trials (RCTs), pooled individual patient data from RCTs, nonrandomized multicenter clinical trials, and observational studies that used strategies to reduce bias (adjustment, stratification, matching, or propensity scores).

For Key Questions 2 and 3 the EPC defined efficacy and effectiveness trials following criteria from the Comparative Effectiveness Reviews (CER) manual. They compared the results from observational studies and RCTs on positive clinical outcomes and harms. They included RCTs that combined men and women if they reported outcomes in women separately or included more than 75 percent women. The EPC examined unpublished RCTs from the medical and statistical reviews that were conducted by the FDA. They included observational studies of treatments that were not examined in RCTs.

Exclusion Criteria

- Studies of children, adolescents, or men.
- Studies of incontinence caused by neurological disease.
- Studies of dual fecal and UI.
- Studies of surgical treatments for UI or urogenital prolapsed.
- Studies of drugs not available in the United States.
- Studies with no clinical outcomes relevant to UI.
- Case series with fewer than 100 subjects that reported short-term (less than 4 weeks) crude rates of the outcomes and/or did not use strategies to reduce bias.
- Secondary data analysis, nonsystematic reviews, letters, or comments.
- Studies that reported absolute values of the diagnostic tests in incontinent women.
- Studies that did not report true and false positive and negative cases of diagnostic tests.

To assess harms of the treatments we followed the recommendations from the CER manual and reviewed published and unpublished evidence of the adverse effects of eligible drugs and nonsurgical treatments for female urinary incontinence including:

- Randomized controlled trials.
- Unpublished supplemental trials data from the Web site <http://www.clinicalstudyresults.org> .
- Observational cohort and case control studies.
- Observational studies based on patient registries or large databases.
- Case reports and post-marketing surveillance.

The EPC defined harms as the totality of all possible adverse consequences of an intervention. They analyzed harms regardless of how authors perceived the causality of treatments.

The EPC did not contact the investigators of the primary studies.

Number of Source Documents

- 749 therapeutic studies were included in the original review
- The updated literature search found 31 eligible publications

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Quality of Evidence

High-Quality Evidence: Evidence is considered high quality when it is obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change our confidence in the estimate of effect.

Moderate-Quality Evidence: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on our confidence in the estimate of effect and may change the estimate.

Low-Quality Evidence: Evidence obtained from observational studies would typically be rated as low quality because of the risk for bias. Low-quality evidence means that further research is very likely to have an important effect on our confidence in the estimate of effect and will probably change the estimate. However, the quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence

is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose-response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

Insufficient Evidence to Determine Net Benefits or Risks: When the evidence is insufficient to determine for or against routinely providing a service, the recommendation was graded as "insufficient evidence to determine net benefits or risks." Evidence may be conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect that is very uncertain as evidence is either unavailable or does not permit a conclusion.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Minnesota Evidence-based Practice Center (EPC) (see the "Availability of Companion Documents" field).

Quality Assessment

The EPC rated the quality of studies according to recommendations from the Methods Guide for Effectiveness and Comparative Effectiveness Review. They classified the studies by design to distinguish randomized and nonrandomized controlled clinical trials from observational studies. They evaluated the quality of therapeutic studies using predefined criteria, which included randomization, adequacy of randomization and allocation concealment, masking of the treatment status, intention to treat principles, and justification of the sample size. The EPC evaluated disclosure of conflict of interest by the authors of individual studies and funding sources but did not use this information to downgrade quality of individual studies. They did not downgrade methodological quality of poorly reported studies. They did synthesize evidence from poorly reported studies separately.

The EPC defined well-designed randomized controlled trials (RCTs) with adequate allocation concealment, intention to treat principles in analysis, and appropriate measurements of clinically important outcomes as studies with low risk of bias.

The EPC defined studies as having a medium risk of bias if they were susceptible to some bias but not sufficient bias to invalidate the results. Examples of studies with medium risk of bias include open label RCTs, RCTs with unclear allocation concealment, RCTs with a short term of follow-up, and crossover RCTs without assessment of carryover effect.

The EPC defined studies as having a high risk of bias if they had significant flaws that imply biases of various types that may invalidate the results, including nonrandom treatment allocation, no strategies to reduce bias, and ignoring randomization in analysis.

Grading the Evidence for Each Key Question

The EPC assessed strength of evidence following the guidelines in the Comparative Effectiveness Reviews (CER) Manual. They judged the strength of evidence according to the domains of risk of bias, consistency, directness, and precision for each major outcome. When appropriate, they also included dose response association, presence of confounders that would diminish an observed effect, and strength of association. The EPC evaluated strength of the association defining a priori large effect when relative risk was >2 or <0.5 and very large effect when relative risk was >5 or <0.2 . They defined low magnitude of the effect when relative risk was significant but less than 2.

The EPC defined evidence as strong when several well-designed RCTs with a low risk of bias demonstrated consistent treatment effects. These are findings for which future research would be very unlikely to change the estimate of effect. They assigned a moderate level of evidence when RCTs with medium risk of bias reported consistent treatment effects or large observational studies reported consistent associations. The EPC assigned a low level of evidence to data from RCTs with serious flaws in design/analysis, and from post hoc subgroup analysis; these are findings for which further research is likely to change the estimate. They defined insufficient evidence when a single study examined treatment effects or associations. The EPC graded the level of evidence for primary outcomes across studies as illustrated in Table 2 in the evidence review (see the "Availability of Companion Documents" field).

Applicability

Applicability of the population was estimated by evaluating the female population from which samples have been selected in observational studies and clinical trials. The EPC examined settings of the studies including ambulatory care or specialized clinics, recruitment in clinical settings or in the community, inclusion age and type of urinary incontinence (UI), and exclusion criteria for each study.

The studies that recruited women from the population had better applicability. The EPC assumed the presence of publication bias and did not use statistical tests for bias defined as the tendency to publish positive results. They used several strategies to reduce bias, including a comprehensive literature search of published and unpublished evidence in several databases, reference lists of systematic reviews, proceedings of scientific meetings, contacts with experts for additional references, and agreement on the eligibility status by several investigators.

Data Extraction

Four researchers manually and independently performed evaluations of the studies and data extraction. The data abstraction forms are shown in Appendix E in the evidence review (see the "Availability of Companion Documents" field). They did multiple quality controls of all data from RCTs and in a 30 percent random sample of observational studies. Errors in data extractions were assessed by a comparison with the established ranges for each variable and the data charts with the original articles. Any discrepancies were detected and discussed. They abstracted the number of positive (true and false) and negative (true and false) after index diagnostic tests when compared to multichannel urodynamics or diary. They abstracted descriptive information about populations, interventions, controls, outcomes, settings, and time to measure outcomes in relation to the randomization or beginning of the treatment. They abstracted the number randomized into active and control treatments, doses of the drugs, events or rates, or means and standard deviations after active and control treatments. They abstracted and conflict of interest by the authors of the studies. They abstracted inclusion of minorities in the studies, inclusion of women who failed prior therapy for UI, inclusion of mixed UI, baseline daily UI, and presence of urogenital prolapse or hysterectomy in women who participated in the studies. Adjustments for age, race, comorbidities, socioeconomic status, previous treatments, and baseline severity of UI were extracted from observational studies.

Data Synthesis

For Key Questions 2 and 3 the EPC calculated relative risk, absolute risk differences, number needed to treat (NNT), and the number of events attributable to active treatment per 1,000 persons treated for binary outcomes. They used the number of randomized subjects forcing intention to treat principles independent of the ambulatory studies analyses. They calculated mean differences from the reported means and standard deviations among randomized to active and control treatments. The EPC used correction coefficients, forced intention to treat, and recommended calculations for missing data. They used Meta-Analyst and STATA (Statistics/Data analysis, 10.1) software to calculate individual study estimates with a 95 percent confidence interval (CI).

Following guidelines and recommendations from key informants and members of our Technical Expert Panel, the EPC focused on patient-centered outcomes including continence, improvement in UI, quality of life, adverse effects, and discontinuation due to adverse effects. The EPC used the definitions of signs and symptoms of UI promoted by the International Urogynecological Association (IUGA)/International Continence Society (ICS) (see Appendix Table D2 in the evidence review [see the "Availability of Companion Documents" field]), including mixed, stress, and urgency UI. They defined continence when the authors reported cure, absence of incontinent episodes in bladder diaries, or negative pad or stress tests (see Table 1 in the evidence review [see the "Availability of Companion Documents" field]). The EPC defined improvement in UI when the authors reported reduction by more than 50 percent in frequency of UI in diaries or patient-reported significant improvement in UI. They defined failure when frequency of UI did not change or became worse in diaries or according to patient reported worsening of UI. The EPC relied on patient outcomes rather than continuous measures of UI episodes or urine loss. They analyzed discontinuation rates independent of investigator judgments about association with tested drugs. They analyzed adverse effects as reported by the authors.

Pooling criteria included the same operational definitions of clinical populations, incontinence outcomes, the same clinical interventions, and the time of the assessment of the outcomes. Meta-analysis was used to assess the consistency of the association between treatments and incontinence outcomes with random effects models using an inverse variance weighting method (see Appendix Table D5 in the evidence review [see the "Availability of Companion Documents" field]). The EPC chose the random effects model to incorporate in the pooled analysis differences across trials in patient populations, baseline rates of the outcomes, dosage of drugs, and other factors. For pooled relative risks (RR) and absolute risk difference (ARD) they excluded trials with no events in both groups and added a correction coefficient of 0.5 in the trials with no events only in one group. The EPC used pooled ARD to calculate the number needed to treat and the number of events attributable to active treatment per 1,000 persons treated. They calculated means and 95 percent CI for the number needed to treat as reciprocal to pooled ARD when ARD was significant. They calculated means and 95 percent CI for treatment events per 1,000 treated, multiplying pooled absolute risk difference by 1,000. The EPC assessed missing data across studies, including loss to follow-up and dropout patterns, and forced intention-to-treat analysis using the number of randomized subjects for all calculations. They also used maximum likelihood method for pooling continence, clinically important improvement in UI, and treatment discontinuation due to adverse effects. The EPC calculated split placebo sample sizes and events in multi-arm drug trials proportionally to the randomization ratio to avoid double counting control groups. They synthesized sparse data defined as rates less

than 2 percent by calculating fixed Mantel-Haenszel relative risk, and Peto odds ratio. They analyzed adverse effects with drugs for urgency UI using double arcsine transformation for event rates. When studies had no events with active, control, or both treatments, the EPC used correction coefficients and calculated odds ratios from random-effects generalized nonlinear mixed-effect models.

The EPC examined the association between age, race, obesity, comorbidities, UI type, baseline severity, and response to prior treatments with clinical outcomes as reported by the authors of the original studies. They synthesized the evidence by the baseline type of UI as pure or predominant stress, pure or predominant urgency, and mixed UI. The EPC compared clinical outcomes by the type of UI within each study and across the studies. They evaluated inclusion and exclusion criteria and baseline characteristics of the subject to determine whether all or a proportion of the subjects had mixed UI. Then the EPC conducted quantitative meta-regression and subgroup analysis to determine treatment effects by baseline type of UI. When exploring heterogeneity, they did not use subject level variables to avoid an ecological fallacy.

The EPC examined consistency in results across the studies with Chi square tests and I square statistics. They explored heterogeneity with meta-regression, subgroup, and sensitivity analysis and reported the results from random effects models only. Using a standard preplanned algorithm, they explored heterogeneity by clinical diversity, comprised of the proportion of women, proportion of minority population, age of women, severity of UI, failure after prior treatments, concomitant treatments, inclusion of women with urogenital prolapse, and inclusion of women with mixed UI. The EPC explored heterogeneity by dose (when applicable), by duration of the treatments, and by control rate of the outcomes. They explored heterogeneity by quality criteria of individual studies and by whether conflict of interest was disclosed by study authors. They explored heterogeneity by each quality criterion rather than the global quality score. They calculated pooled relative risk, absolute risk difference with 95 percent CI, and Bayesian odds ratios with 95 percent credible intervals using STATA 10.1 and Meta-Analyst software. The EPC analyzed the probability that active treatments increased the chances of continence, improvements of UI, or adverse effects with the Bayesian approach using noninformative prior probability of the events. The analytic framework and algorithms for the meta-analysis are shown in Appendix Table D5 in the evidence review (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline is based on a systematic evidence review that addressed the following key questions related to the diagnosis and nonsurgical management of urinary incontinence (UI):

1. How effective is the nonpharmacologic treatment of UI in women?
 - a. How do nonpharmacologic treatments affect incontinence, severity and frequency of UI, and quality-of-life compared with no active treatment?
 - b. How do combined methods of nonpharmacologic treatments with drugs affect incontinence, severity and frequency of UI, and quality-of-life compared with no active treatment or monotherapy?
 - c. What is the comparative effectiveness of different nonpharmacologic treatments?
 - d. What are the harms of nonpharmacologic treatments compared with no active treatment?
 - e. What are the comparative harms of different nonpharmacologic treatments?
 - f. Which patient characteristics, including age, type and severity of UI, baseline disease that affects UI, adherence to treatment recommendations, and comorbid conditions, can modify the effects of nonpharmacologic treatments on patient outcomes, such as continence, quality of life, and harms?
2. How effective is the pharmacologic treatment of UI in women?
 - a. How do pharmacologic treatments affect continence, severity and frequency of UI, and quality-of-life compared with no active treatment or combined treatment methods?
 - b. What is the effectiveness of pharmacologic treatments compared with each other or with nonpharmacologic treatments of UI?
 - c. What are the harms of pharmacologic treatments compared with no treatment?
 - d. What are the harms of pharmacologic treatments of UI compared with each other or with nonpharmacologic treatments?
 - e. Which patient characteristics, including age, type and severity of UI, baseline disease that affects UI, adherence to treatment recommendations, and comorbid conditions, can modify the effects of pharmacologic treatments on patient outcomes, such as continence, quality of life, and harms?

This guideline rates the evidence and recommendations by using the American College of Physicians' (ACP's) guideline grading system (see the

"Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields). Details of the guideline development process can be found in the summary of methods paper (see the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

The American College of Physicians Guideline Grading System*		
Quality of Evidence	Strength of Recommendation	
	Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits	Benefits Finely Balanced with Risks and Burden
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or risks		

*Adopted from the classification developed by the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) workgroup.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was approved by the American College of Physicians (ACP) Board of Regents on September 25, 2013.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate management of women with urinary incontinence (UI)
- See the systematic review (see the "Availability of Companion Documents" field) for additional information on the benefits and harms of pharmacologic treatment.

Potential Harms

- Low-quality evidence from one study showed that higher doses of solifenacin (10 mg/d vs. 5 mg/d) did not decrease the frequency of urinary incontinence (UI) episodes and were associated with increased risk for adverse effects.
- Patients receiving 7 or more concomitant medications had more adverse effects than those receiving fewer than 7.
- Appendix Table 2 in the original guideline document summarizes the adverse effects associated with pharmacologic treatments.
- Discontinuation of treatment due to adverse effects was common.
- See the systematic review (see the "Availability of Companion Documents" field) for additional information on the benefits and harms of pharmacologic treatment.

Qualifying Statements

Qualifying Statements

- Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.
- The authors of this article are responsible for its contents, including any clinical or treatment recommendations. No statement in this article should be construed as an official position of the U.S. Department of Veterans Affairs.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Patient Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P, Clinical Guidelines Committee of the American College of Physicians. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2014 Sep 16;161(6):429-40. [163 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Sept 16

Guideline Developer(s)

American College of Physicians - Medical Specialty Society

Source(s) of Funding

Financial support for the development of this guideline comes exclusively from the American College of Physicians (ACP) operating budget.

Guideline Committee

Clinical Guidelines Committee of the American College of Physicians

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Disclosures

Dr. Dallas reports support for travel to meetings for the study or other purposes from the American College of Physicians and stock/stock options from Pfizer, Ortho-McNeil, Sanofi-Aventis, GlaxoSmithKline, and Merck. Dr. Shekelle reports personal fees from ECRI Institute and the U.S. Department of Veterans Affairs; grants from the Agency for Healthcare Research and Quality, U.S. Department of Veterans Affairs, Centers for Medicare & Medicaid Services, and Office of the National Coordinator for Health and Information Technology; and a patent with royalties paid to

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Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

Availability of Companion Documents

The following are available:

- Updated literature search for pharmacologic treatments for urgency UI. Supplemental content. 2014. 60 p. Available from the [Annals of Internal Medicine Web site](#) .
- Benefits and harms of pharmacologic treatment for urinary incontinence in women: a systematic review. *Ann Intern Med*. 2012 Jun 19;156(12):861-74. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .
- Shamlivan T, Wyman J, Kane RL. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative effectiveness review no. 36. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2007-10064-I). AHRQ publication no. 11(12)-EHC074- EF. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2012 Apr. 1104 p. Electronic copies: Available from the [AHRQ Web site](#) .
- Qaseem A, Snow V, Owens DK, Shekelle P. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. *Ann Intern Med*. 2010 Aug 3;153(3):194-9. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

A collection of Recommendation Summaries for all current ACP Clinical Guidelines is available for mobile devices from the [ACP Web site](#) .

A continuing medical education (CME) is available from the [Annals of Internal Medicine Web site](#) .

Patient Resources

The following is available:

- Summaries for patients. Nonsurgical management of urinary incontinence in women: a clinical practice guideline. Ann Intern Med. 2014 Sep 16;161(6):I-34. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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